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Remarks

Claims 6 through 8 and 12 through 20 remain pending in the application.

Applicant has amended claims 6, 7, 12, 13, 15, 18 and 19 to correct grammatical or typographical errors. The substance of the claims has not changed.

35 U.S.C. 103(a) Rejections

The Office Action rejects claims 6 through 8 and claims 12 through 20 under 35 U.S.C. 103(a) as being obvious over Woudenberg et al., Cardiopulmonary Resuscitator, U.S. Patent 4,664,098 (May 12, 1987). The Office Action asserts that Woudenberg shows all the structural and functional limitations of the invention but does not specify the material choice and does not show a larger bladder. The Examiner further asserts that the material choice or size are considered obvious choices of design, either known in the art or based on user preference to suit particular applications.

Applicant points out that the Examiner did not respond to the arguments presented in the previous Office Action against using Woudenberg as a reference to support an obviousness rejection. Applicant respectfully requests that the Examiner fully consider all of the following arguments.

The Office Action's assertion that material choice or size is an obvious design choice is improper as a substitute for the required analysis of patentability. The case of <u>Graham v. John</u> <u>Deere Co.</u>, 383 U.S. 1 (1966), eliminates application of all such maxims in favor of the mandated test for patentability. The mere statement that, in any one person's opinion, a given element is an

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"obvious design choice" does not accomplish the legally required inquiry. There is no rational basis for application of such an assertion, and thus the assertion deprives the applicant of his right to have his application considered under uniform standards on par with all other applicants. Therefore the rejection is improper and should be withdrawn.

Case law mentioning the design choice issue indicates that the rejection stems from a fundamental misunderstanding of the patent law. For example, <u>In re Chu</u>, 66 F.3d 292 (Fed. Cir. 1995) indicates that a rejection based on design choice can be overcome by supplying evidence that the claimed combination is somehow better than the prior art. However, under United States patent law there is no requirement that an applicant's claimed invention be "better" than the prior art: it must be novel and non-obvious. See 35 U.S.C. 101, subject to 35 U.S.C. 102 and 103. An extremely valuable invention may be far worse than the prior art, but patentable nonetheless. For example, a modern tracheotomy instrument is "better" than a ballpoint pen for performing tracheotomies. However, if a ballpoint pen is all that is available for treatment during an emergency then it is nevertheless extremely valuable. If there is no suggestion in the art to use a ballpoint pen to perform a tracheotomy, then the method should be patentable, notwithstanding the universal understanding that such a method is generally inferior to the prior art. It is thus clear that the design choice rule and the ability to overcome it by showing superiority over the prior art are improper rules.

Even if the "design choice" rejection were proper, Woudenberg teaches away from the claims. Woudenberg discloses a 10 centimeter (4 inch) belt, see column 5, lines 45-52. Woudenberg specifically states that, "We have found this width of belt to be particularly suitable as it prevents substantial rocking of the mounting means, i.e. during operation of the apparatus." From

this language it is easily understood that Woudenberg requires a relatively narrow belt. Thus, the width of the belt is not a "mere design choice" as asserted by the Office Action. On the other hand, all of Applicant's claims require that the belt be sized to cover a substantial portion of the patient's chest. Thus, Woudenberg teaches away from Applicant's claims.

In addition, in Applicant's experience a narrow belt, as taught by Woudenberg, would saw the patient's body as it performs hundreds of compressions over the course of the time required for a typical treatment. The sawing action may produce severe lacerations about the edges of the belt. By using a wider belt applicant reduces the pressure about the edges of the belt and thus alleviates the problem of sawing. This fact demonstrates that the choice of belt is not one of design or material choice, contrary to the assertion of the Office Action.

Moreover, the physical interaction between the belt and the body of the patient is not readily understood, insofar as it is not possible to predict the effect of various changes in components and parameters on the resultant blood flow. Thus, there is no motivation to make any changes to the bladder shown in Woudenberg. Woudenberg teaches application of force over a 4 inch circular region over the xyphoid process, coincident with the point at which manual CPR is applied. It is clear that the resultant point force compression might cause cardiac compression

¹ The time for a typical treatment is estimated at about ten minutes to an hour. This estimate is based on the time required for EMS personnel to respond to an emergency and transport the patient to a hospital. At ten minutes the belt, at 80 compressions per minute, would perform 800 compressions. At one hour the belt would perform 4,800 compressions. Given the force required to compress the patient's sternum for effective CPR, the effect of "sawing" the patient with a securing belt is a non-trivial problem.

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comparable to manual CPR. Merely changing the size of the Woudenberg components will have no certain effect on the degree to which the heart is compressed. It may well have a deleterious effect if the bladder is merely enlarged to the extent necessary to partially cover the ribs, which are less compliant than the area over the xyphoid process. Thus, the suggestion that changes in size of the components is a matter of design choice is unfounded

Because Woudenberg teaches away from Applicant's claims and because there is no motivation to make any changes to the Woudenberg bladder, Woudenberg is inapplicable as a reference to establish the obviousness of Applicant's claims. Accordingly, Applicant requests reconsideration and allowance of the claims.

Regarding claim 15 and claim 18, the rejection ignores limitations of the claims. Claim 15 requires that the bladder be wider than the belt. The relative sizes of the belt and the bladder are not addressed in the rejection. Claim 18 requires that the bladder be detachable from the belt. There is no motivation to make either of these modifications to Woudenberg. Accordingly, Applicant requests reconsideration and allowance of claims 15 and 18.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

Date: November 2, 2001

By:

K. David Crockett, Esq.

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